U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Application for Continuation of a Grant (PHS 2590)

I. SUBMITTING YOUR APPLICATION

Applications to continue support of a PHS grant must be submitted to the awarding component's grants management office on PHS 2590 two months before the beginning date of the next budget period. The Data Management Branch/EIS in the Office of Policy for Extramural Research Administration, OER, NIH, will mail a computer-generated Face Page (Form Page 1) and appropriate mailing labels to the applicant organization approximately four months before the end of the current budget period. If you do not receive a computer-generated Face Page, call the Data Management Branch at (301) 435-0896. Using the mailing label provided, submit the completed, signed original application and two copies (with required signatures) directly to the awarding component that is funding the grant. You may substitute computer-generated facsimiles for any of the forms, except for the computer-generated Face Page. Substitute forms should be printed in black ink, and maintain the exact wording and format of the government-printed forms, including all captions and spacing. Any questions on completing this continuation application should be directed to the awarding component.

Note that this packet contains sample application forms only. Blank form pages are available separately from the applicant's office of sponsored research and on the NIH Web site. Investigators are encouraged to retain these instructions for future submissions. The NIH does not distribute any software for computer generation of the application. However, the forms, in Adobe Acrobat, can be downloaded from the NIH Web site at http://www.nih.gov/grants/forms.htm. Future developments in electronic transfer of applications will be published periodically in the *NIH Guide for Grants and Contracts.*

GrantsInfo, DEOIR, OER, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. The NIH grants Web site is at **http://www.nih.gov/grants/oer.htm**. The e-mail address is: GrantsInfo@nih.gov. The phone number is: (301) 435-0714.

Use English only and avoid jargon and unusual abbreviations. Prepare the application, single-sided and single-spaced, staying within the margin limitations indicated on the form.

The application must be clear, readily legible, and conform to the following three requirements: 1) The height of the letters must not be smaller than 10 point; 2) Type density must be no more than 15 cpi (characters per inch). For proportional spacing, the average for any representative section of text must not exceed 15 cpi; and 3) No more than 6 lines of type must be within a vertical inch. Type requirements should be checked on the printed document using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size used throughout the application must conform to all three requirements.

Do not bind or staple the original. An incomplete or incorrectly prepared continuation application may result in a delay in award of funds.

PHS estimates that it will take approximately 15 hours to complete this application for a regular research project grant. Items such as human subjects are cleared and accounted for separately, and are not part of the time estimate for

completing this form. If you have comments regarding the burden estimate or other aspect of the collection of information, including suggestions for reducing the burden, send comments to: NIH, Project Clearance Office, 6701 Rockledge Drive MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0001). Do not send applications to this address.

II. PREPARING YOUR APPLICATION

A. Streamlined Noncompeting Award Process (SNAP)

The NIH has developed this simplified process for the submission of information prior to the issuance of a noncompeting award. For additional information on completing any part of PHS 2590, refer to the Specific Instructions (Section B). When additional information is required, use the appropriate form page. For example, the biographical sketch page is still required for new key personnel.

These simplified instructions apply to all grant mechanisms routinely covered under expanded authorities and Federal Demonstration Partnership terms and conditions, except for Program Project Grants (P01s) and Outstanding Investigator Grants (R35s). NIH routinely applies expanded authorities to Program Project Grants (P01s), Minority High School Student Research Apprentice Program Awards (S03s), Research Career Awards (K-Series), and all Research Project Grants (R-Series), except Phase I Small Business Innovation Research (R43) and Small Business Technology Transfer (R41) Awards. Any award excluded from expanded authorities is routinely excluded from SNAP. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Complete the Face Page (Form Page 1) except for items 9a and 9b, the Progress Report Summary (Form Page 5), and the Personnel Report (Form Page 7). Complete the Checklist Page (Form Page 6) only if there is a change in performance site(s) that will affect facilities and administration (indirect) costs and/or if program income is anticipated. If program income is anticipated, the application should reflect the amount and source(s). The Progress Report should begin on Form Page 5. Complete all information and provide a brief, two page, progress report following the instructions, which begin on page 7 of these instructions. Tables and figures that summarize key accomplishments are not counted in the two page limit.

Answer the following questions at the beginning of Form Page 5. Blank pages should be used for the Progress Report if inadequate space remains on Form Page 5 to answer the questions and to begin the report on the research progress. The questions to be addressed are as follows:

- ***Has there been a change in the other support of key personnel since the last reporting period?*** If yes, explain the change(s); if no, so state. Specific information is to be provided only if active support has changed. If a previously active grant has terminated and/or if a previously pending grant is now active, the change in support is to be reported. Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously. Other support information should be submitted only for the principal investigator and for those individuals considered by the principal investigator to be key to the project. Key personnel is defined as an individual who contributes in a substantive way to the scientific development or execution of the project, whether or not a salary is requested. Key personnel is defined in the PHS 398 application instructions.

- ***Will there be, in the next budget period, significant rebudgeting of funds from what was approved for this project?*** If yes, please explain; if no, so state. Significant rebudgeting occurs when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established at the time of the competing award by more than 25 percent of the total amount (direct and F&A Costs) awarded for the budget period. The basis for determining significant rebudgeting excludes the effects of carryover of prior year unobligated balances, but includes competing or administrative supplements.

- ***Will there be, in the next budget period, a change in the level of effort for key personnel from what was approved for this project?*** If yes, please explain; if no, so state. A significant change in level of effort is defined in Federal regulations as a 25 percent reduction in time devoted to the project. For example, if a key person on the project is expected to reduce his/her effort from 40 percent to 30 percent, which represents a 25 percent reduction in the level of effort, an explanation must be provided at the beginning of the Progress Report Summary (Form Page 5).

- *Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?* If yes, please provide an explanation; if no, so state. An explanation should include why there is a significant balance and how it will be spent if carried forward into the next budget period.

Program or grants management staff may require additional information in order to evaluate the project for continued funding. Failure to provide this information will result in a delayed award.

If a project or grantee organization requires closer monitoring by NIH staff, the project or organization may not use these simplified instructions.

If you have any questions, contact the grants management specialist identified on the current Notice of Grant Award.

B. Specific Instructions

1. Face Page

Items 1-6. The computer-generated Face Page (Form Page 1) has information already preprinted through Item 6. Complete and use this as the final copy. Add the electronic mail address information, if applicable. Check the preprinted material carefully and, when necessary, make corrections by entering the item number and the correct information under Item 13. Do **not** use Item 13 to indicate change of applicant organization. Form PHS 398 **must** be used in such cases. Contact the awarding component for further instructions.

(Note: If the preprinted copy is not provided, or extensive corrections are necessary, use Page 1 in the form booklet.)

Item 3. Organizational Component. If the scientific and administrative responsibility for a research grant has changed from one organizational component to another, make the necessary correction in Item 13 on the computer-generated Face Page, using both the code and identification below.

| Academic Institutions | | Nonacademic Institutions | |
Code	Identification	Code	Identification
01	School of Medicine	30	Hospital
03	School of Dentistry	52	Health Department
05	School of Osteopathy	60	Research Organization
07	School of Pharmacy	70	Other Nonacademic
09	School of Nursing		
11	School of Veterinary Medicine		
13	School of Public Health		
14	School of Optometry		
15	School of Allied Health		
16	College of Podiatric Medicine		
20	Other Academic		

Item 6. Administrative Official. If the institutional representative to be contacted for additional information has changed, make the necessary corrections in Item 13 on the computer-generated Face Page and provide the name, telephone, and fax in Item 12b.

Item 7. Human Subjects. Policy on research involving human subjects can be found in the *PHS Grants Policy Statement* or the PHS 398 application instructions. If activities involving human subjects are **not** planned **at any time** during the proposed budget period, check "No." The remaining parts of Item 7 are then not applicable.

If activities involving human subjects, whether or not exempt from the Federal regulations for the protection of human subjects, are planned **at any time** during the budget period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes." If the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories listed in the *PHS Grants Policy Statement* or the PHS 398. The remaining parts of Item 7 are then not applicable. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in an award. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category. In doubtful cases, consult with the Office for Protection from Research Risks (OPRR), National Institutes of Health, Rockville, MD 20892, (301) 496-7041, or the program administrator in the awarding component.

If the planned activities involving human subjects are not exempt, complete the remaining parts of Item 7. If the applicant organization has an approved Multiple Project Assurance of Compliance on file with the OPRR that covers the specific activity, insert the Assurance number and the latest date of approval by the Institutional Review Board (IRB) of the proposed activities. This date must not be earlier than one year before the start date for which the application is submitted. **No application for continuation support should be submitted until the necessary certification of annual review has been obtained.**

Check the type of IRB review in the appropriate box. An IRB of an institution with a Multiple Project Assurance may review an application through an expedited review procedure only if it complies with Section 46.110 of the human subject regulations 45 CFR 46.

Item 8. Vertebrate Animals. Policy on research activities involving vertebrate animals can be found in the *PHS Grants Policy Statement* or the PHS 398 application instructions. If activities involving vertebrate animals are **not** planned **at any time** during the proposed budget period, check "No." The remaining parts of Item 8 are then not applicable.

If activities involving vertebrate animals are planned **at any time** during the budget period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes." If the applicant organization has an approved Animal Welfare Assurance on file with OPRR, insert the Assurance number at Item 8b. In addition, provide the latest date of approval by the Institutional Animal Care and Use Committee (IACUC). **No application for continuation support should be submitted until the necessary verification of review has been obtained**.

Item 9a. Direct Costs Requested for Next Budget Period. Enter the direct costs from Form Page 2.

Item 9b. Total Costs Requested for Next Budget Period. Enter the sum of the total direct costs from Item 9a and F&A costs.

Item 10. Inventions and Patents. If no inventions were conceived or reduced to practice during the course of work under this project, check "No."

If any inventions were conceived or reduced to practice during the course of work under this project, check "Yes." Check the appropriate box to indicate whether this information has or has not been previously reported to the PHS or to the official responsible for patent matters in the applicant organization.

Recipient organizations must report these inventions promptly to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-7750, (301) 435-1986. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the applicant institution, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

Item 11. Performance Sites. Indicate where the work will be conducted. If there is more than one performance site, list all the sites, including VA facilities and foreign sites. Additional continuation pages may be used, as necessary, immediately following the Face Page. Number the pages consecutively.

Item 12. Telephone and Fax Information. Self-explanatory.

Item 13. Use this space for corrections and changes.

Item 14. Principal Investigator/Program Director Assurance. Self-explanatory.

Item 15. Applicant Organization Certification and Acceptance. In signing the Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications listed on the following page. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and

Administration cost rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant-supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances/Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing For Applicant Organization on the Face Page of the application. Definitions are provided in the *Grants Policy Statement* and in the PHS 398 application instructions.

> Human Subjects
> Vertebrate Animals
> Debarment and Suspension
> Lobbying
> Delinquent Federal Debt
> Research Misconduct
> Civil Rights
> Handicapped Individuals
> Sex Discrimination
> Age Discrimination
> Financial Conflict of Interest

2. Detailed Budget for Next Budget Period (Form Page 2)

Itemize the direct costs requested for the next budget period by budget categories. Use the recommended direct cost shown on the spreadsheet included with the Notice of Grant Award issued in the competitive year as the guide for developing the line item annual budget. Use Form Page 3 and continuation pages as necessary to provide required explanation of budget items.

For multiproject grants whose individual projects are budgeted separately, additional copies of Form Page 2 should be prepared for each project or core in the program. Number these pages consecutively. Do not use suffixes such as 2a, 2b. On the individual budget pages for each specific

project, clearly identify the name of the project leader and the title of the project.

Certain conditions may change the funding requirements for a budget period from those originally recommended. Such proposed funding changes, particularly increases over the recommended level, must be explained and fully justified for PHS awarding component consideration.

Name and Role on Project

Starting with the principal investigator, list all employees of the applicant organization who will be involved on the project, regardless of whether or not salaries are requested.

Type of Appointment/Months

List the number of months per year reflected in an individual's contractual appointment to the applicant organization. **PHS staff assume that appointments at the applicant organization are full time for each individual.** If an appointment is less than full time, e.g., 50 percent time, identify with an asterisk (*) and provide a full explanation under Justification on Form Page 3. Individuals may have split appointments, for example for an academic period and a summer period. For each appointment, identify and enter the number of months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for that period.

Percent of Effort on Project

For each individual at the applicant organization, list the percent of each appointment to be spent on this project.

Salary Requested

Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's base salary, up to any imposed salary limitation, by the percent of effort on the project. Explain under Justification on Form Page 3 if a lesser amount is requested, e.g., endowed position, institutional sources, or other support.

Fringe Benefits

Fringe benefits may be requested in accordance with the institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals

Calculate the totals for each position and enter the subtotals in each column where indicated.

Special Instructions for Individuals with Joint University and Department of Veterans Affairs Appointments

Individuals may request the university's share of the salaries in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that salary request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the Department of Veterans Affairs (VA); and (2) there is no possibility of dual compensation for the same work, or an actual or apparent conflict of interest regarding such work.

For applications under joint-appointment conditions, do the following:

Type of Appointment/Months — List the number of months per year reflected in the university appointment. Identify with an asterisk (*) and provide a full explanation about the individual's total responsibilities under the joint appointment on Form Page 3. Specify the title of each appointment, the types of responsibilities (teaching, research, clinical, consulting, and administration), and the proportion of each to the total set of responsibilities.

Percent of Effort on Project — List the percentage of the university appointment that is to be devoted to this project.

For VA responsibilities, complete on a separate line the type of appointment and percent of effort.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Briefly describe on Form Page 3 any changes in services to be performed. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment

List separately each item of equipment and justify the purchase on Form Page 3, if not previously approved.

Supplies

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

Travel

Itemize travel requests and justify on Form Page 3. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

Patient Care Costs

Indicate the basis for estimating costs in this category in detail, including the number of patient days, estimated cost per day, and cost per test or treatment. If both in-patient and out-patient costs are requested, provide information for each separately, and if multiple sites are to be used, provide the information in detail by site.

Include information regarding projected patient accrual for the budget period and relate this information to the budget request for patient care costs.

Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include potential or expected utilization of General Clinical Research Centers.

Patient care costs do **not** include travel, lodging, and subsistence or donor/volunteer fees. Request these costs in the Other Expenses category. Request consultant physician fees in the Consultant Costs category. Patient care costs will be provided to foreign organizations only in exceptional circumstances.

Alterations and Renovation

Itemize by category and justify on Form Page 3 the costs of essential alterations and renovations, including repairs, painting, removal or installation of partitions, shielding, or air conditioning. When applicable, indicate the square footage involved, giving the basis for the costs, such as an architect's or contractor's detailed estimate as outlined by the

PHS Grants Policy Statement. Line drawings of the proposed alterations should be submitted with the application where required by the *PHS Grants Policy Statement.* Costs for alterations and renovations are not allowed on grants made to foreign organizations.

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary.

Consortium/Contractual Costs

Each participating consortium/contractual organization must submit a separate detailed budget (Form Page 2) and budget justification (Form Page 3) for the next budget period. If a new consortium is added, follow the guidelines in the PHS 398 application instructions.

List the Facilities and Administration (F&A) costs, if any, and provide the basis for the rate in the Consortium/Contractual Costs category. Insert the page(s) for each consortium/contractual organization after Form Page 3 and number them consecutively.

The sum of all consortium/contractual costs (direct and F&A) must be entered in the Consortium/Contractual Costs category of the applicant organization's budget.

3. Budget Justification (Form Page 3)

Justification

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended.

Current Budget Period

In the space provided, or on additional pages, explain any estimated unobligated balance of total costs (including prior year funds carried over) which is greater than 25 percent of the current year's total authorization or more than $250,000. Explain why there is a significant balance and how it will be spent if carried forward into the next budget period.

4. Biographical Sketch (Form Page 4)

Complete a Biographical Sketch for all **new** key personnel since the previous submission.

Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel.

5. Other Support

For the purposes of the noncompeting continuation application, other support information is **only** required on **active** support for all key personnel. Refer to the PHS 398 application kit for the instructions, definitions, policy, and format pertaining to other support.

6. Progress Report Summary (Form Page 5)

Well-planned Progress Reports can be of great value by providing records of accomplishments, which serve as a basis for continued support of the project. Furthermore, Progress Reports provide information to awarding component staff that is essential in the assessment of changes in scope or research objectives (as defined in the *PHS Grants Policy Statement*) from those actually funded. They are also an important information source for the awarding component staff in preparing annual reports, in planning programs, and in communicating scientific accomplishments to the public and to Congress.

The Progress Report should be a brief presentation of the accomplishments on the research project during the reporting period, in language understandable to a biomedical scientist who may not be a specialist in the project's research field. The style used in *Scientific American* articles would be appropriate. Abbreviations and language that may not be known to the broader scientific community should be avoided unless clearly defined.

When submitting Progress Reports for program project grants, center grants, education grants, or other large multicomponent grants, contact the program official in the awarding component for specific instructions.

The entire Progress Report for regular projects, exclusive of the list of publications, **should not exceed two pages.** The report should follow the outline and numbering system shown below. Continuation pages may be used as necessary.

a. Specific Aims

Because of Scientific Review Group (SRG) and Council recommendations and/or budgetary modifications made by the awarding component, the aims, **as actually funded**, may differ in scope from those stated in the competing application. If the aims have not been modified, state this. If they have been modified, give the revised aims and the reason for the modification.

b. Studies and Results

Describe the studies directed toward specific aims during the current budget year and the results obtained. Include negative results. If technical problems were encountered in carrying out this project, describe how your approach was modified.

Supplements: If applicable, include a separate section(s) describing the results obtained by individuals supported on this grant through various supplements. Examples include a Research Supplement to Underrepresented Minorities, a Research Supplement to Promote the Recruitment of Individuals with Disabilities into Biomedical Research Careers, and/or other similar supplements to support addition of an individual or a discrete project.

c. Significance

Emphasize the significance of the findings to the scientific field and their potential impact on health.

d. Plans

Summarize plans to address the Specific Aims during the next year of support. Include any important modifications to the original plans. Address any changes involving research using human subjects and vertebrate animals.

Complete Items a and b on Form Page 5 if the research involves human subjects or vertebrate animals.

Human Subjects. If the protocols planned for the coming year are different from those proposed in the last application, include an explanation of how they differ and check "Change" on the Progress Report page (Form Page 5). If they are not different, check "No Change" on the Progress Report page. Describe the risks versus benefits to subjects and the importance of the knowledge that may reasonably be expected to result, in accord with the DHHS regulations for protection of human subjects. Where appropriate, indicate whether children are involved in the study or how the study has relevance for conditions affecting children (see PHS 398 Section III. F.1.c, for instructions concerning the Policy of Inclusion of Children).

Vertebrate Animals. If vertebrate animals were not involved in the last application but are now to be included, or if significant changes regarding the use of animals are now proposed, provide a description of the intended involvement of animals in accord with the PHS policy for use of vertebrate animals in research and check "Change" on the Progress Report page. Examples of significant changes might include substituting one animal model for another or changing from noninvasive to invasive procedures. If there has been no change, check "No Change" on the Progress Report page.

e. Publications

List the title and complete references (author(s), journal or book, year, page number) of all publications not previously reported. This includes manuscripts submitted or accepted for publication.

Provide **one copy** of each publication not previously submitted to the awarding component. **Report only those publications resulting directly from this grant.** If there have been no publications, so state.

f. Project-Generated Resources

If the research supported by this grant resulted in data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information available to be shared with other investigators, describe the resource and how it may be accessed.

Gender and Minority Inclusion Table

Inclusion of Gender and Minority Study Subjects. Summarize the study population of the project as actually awarded in terms of sample size and inclusion of participants by gender and ethnic minorities, using Form Page 5.

Provide the number of participants by gender and ethnic minorities enrolled in the study **to date** (cumulatively since the most recent competitive award), using the table on Form Page 5, according to the categories below.

If there is more than one study, provide a separate table for each study. Also report on the subpopulations included in the study.

If the enrollment beginning and end dates are different from those proposed in the last application, include an explanation of how they differ.

Minority Groups. A minority group is a readily identifiable subset of the U.S. population that is distinguished by either racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 defines racial and ethnic categories. NIH has chosen to continue the use of these definitions because they allow comparisons to many national databases, especially national health databases.

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.

Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

Subpopulations. Each minority group contains subpopulations, which are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. These racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

7. Checklist (Form Page 6)

Assurances/Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Definitions are provided in the *Grants Policy Statement* and in the PHS 398 application instructions. If unable to certify compliance where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

> Human Subjects
> Vertebrate Animals
> Debarment and Suspension
> Lobbying
> Delinquent Federal Debt
> Research Misconduct
> Civil Rights
> Handicapped Individuals
> Sex Discrimination
> Age Discrimination
> Financial Conflict of Interest

Program Income: See the PHS 398 application instructions and the *Grants Policy Statement* for information on program income. If no program income is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If program income is anticipated, use the format provided. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.

Facilities and Administration (Indirect) Costs: Follow the instructions on the Checklist.

8. Current Key Personnel (Form Page 7)

(Submit original only. Do not duplicate.)

Using the table, list **all key personnel for the current budget period,** salaried and unsalaried, at the applicant organization or elsewhere, who participated in the project during the current budget period. Include all degrees, role on project, date of birth, annual percent of effort, and Social Security number. When requesting Social Security numbers from personnel, explain that provision of the Social Security number

is voluntary, and the information will be used only for program management purposes.

Place this form at the end of the signed original copy of the application. Do not duplicate.

This is the last page of the application.

Number all pages consecutively.

III. GENERAL INFORMATION

A. Social Security Number

The PHS requests Social Security numbers for accurate identification, referral, and review of applications, and for management of PHS grant programs. Provision of the Social Security number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose his or her Social Security number. The PHS requests Social Security numbers under Sections 301 (a) and 487 of the PHS Act as amended (42 USC 241a and 42 USC 288).

B. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 USC 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder PHS's ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services

(DHHS) and outside the Agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including: Congress acting within its legislative authority; the National Archives; the General Accounting Office; the Bureau of Census; law enforcement agencies; and pursuant to a court order.

Information may also be disclosed outside the Department for the following purposes:

1. To a Congressional office at the request of the record subject;

2. To the Department of Justice as required for litigation;

3. To the cognizant audit agency for auditing;

4. To qualified experts not within the definition of Department employees, as prescribed in Department Regulations (45 CFR 5b.2), for opinions as part of the application review/ award process;

5. For an authorized research purpose under specified conditions;

6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;

7. To a Federal agency, in response to its request, in connection with the letting of a contract or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and

8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

C. Information Available to the Principal Investigator

Under the provisions of the Privacy Act, principal investigators may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. Principal investigators are given the opportunity under established procedures to request that the records be amended if they believe the records are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

D. Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, principal investigator, abstract, and amount of the award.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information which, if disclosed, would be a clearly unwarranted invasion of personal privacy may also be withheld from disclosure. Although the grantee institution and the principal investigator will be consulted about any such release, the final determination will be made by the PHS. Generally available for release, upon request, except as noted above, are: all funded grant applications **including** their derivative funded **noncompeting supplemental** grant applications; pending and funded **noncompeting continuation** applications; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally **not** available for release to the public are: **competing** grant applications (initial, competing continuation, and supplemental) for which awards have **not** been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

Section IV

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Additional Instructions for Preparing Continuation Research Career Award (RCA) Applications

The instructions in this kit are to be used with these additional instructions to request continuation of all research career awards (K series). For those applying under the Streamlined Noncompeting Award Process (SNAP), use the SNAP instructions in Section II.A. beginning on page 2, and the instructions for A.4. through A.7. below. **Supplemental Instructions should be obtained from the awarding component if applicable.**

A. Specific Instructions

1. Detailed Budget for Next Budget Period (Form Page 2)

Personnel

Base the awardee's salary and fringe benefits request on a full-time, 12-month appointment following the guidelines in the appropriate career award instructions. Support for other personnel and amounts in other budget categories may be requested in accordance with applicable career mechanism guidelines.

2. Biographical Sketch (Form Page 4)

Complete for new key personnel if allowable under guidelines for the appropriate K award.

3. Other Support

Following the instructions on page 7, provide the information only for the awardee and sponsor if applicable.

4. Progress Report Summary (Form Page 5)

Follow the instructions for regular research projects found on pages 7-9 using the outline a. through f. Complete information on human subjects and/or vertebrate animals **only** if the awardee has participated in research involving human subjects or vertebrate animals that has

not been reported within the progress report of any other PHS-supported project. In addition, complete items g. through j. below. The awardee completes items g., h., and i.; the individual who has the responsibility for the awardee's research career development completes item j.

  g. **Research Development.** Briefly describe the awardee's involvement in activities during the past year designed to increase research skills. Include formal course work, informal instruction in specific research skills, scientific seminars and meetings, visits to other laboratories, etc. Indicate any changes in key personnel (department head, sponsor, and collaborators) during the past year.

  h. **Other Activities**. Briefly describe the awardee's involvement in activities other than research and research training during the past year, such as teaching, clinical care, professional consultation, service on advisory groups, and administrative activities. Indicate percent of time spent in each of these activities and relationship to the awardee's research career development.

  i. **Research Development and Other Activities Planned for the Next Year**. For the next year of support, provide similar information as that provided in items g. and h., for the past year.

j. Sponsor's Report. Prepare a concise statement of the awardee's progress and performance, during the past year, in terms of development into an independent investigator in the area of the award. The typed name, signature of the sponsor, and date must appear at the end of the Progress Report Summary. For awards without a sponsor/mentor, the person responsible for the candidate's research career development should sign the progress report.

5. Study Subjects

Provide the number of human subjects **only** if the career awardee has participated in research involving human subjects that has not been reported within the Progress Report of any other PHS-supported project.

6. Checklist (Form Page 6)

Facilities and Administration (Indirect) costs on career awards will be awarded at 8 percent of total direct costs.

7. Personnel Report (Form Page 7)

(Submit original Only. Do **not** duplicate.)

Provide the information requested. Place this form at the end of the signed original copy of the application. Do **not** duplicate.

This is the last page of the application.

Number all pages consecutively.

Section V

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Additional Instructions for Preparing a Continuation Application for an Institutional National Research Service Award

Applications to continue support of a PHS Institutional National Research Service Award (NRSA) must be submitted on PHS 2590. The due date for these applications is determined by the awarding component. The Data Management Branch/EIS of the Office of Policy for Extramural Research Administration, OER, NIH, will mail a computer-generated Face Page (Form Page 1) and appropriate mailing labels to the applicant organization approximately two months before the due date of the application.

This section contains additional instructions, a substitute budget page, and a summary of trainees page to be used to request continuation (noncompeting) support under the PHS Institutional NRSA Program. Follow both sets of instructions in preparing your application.

A. Specific Instructions

1. Face Page

Items 1-6. Follow instructions beginning on page 3.

Item 7. Human Subjects. In many instances, trainees supported by institutional training grants will be participating in research projects for which the Institutional Review Board (IRB) review of human subjects is complete or an exemption is designated. This review or exemption designation is sufficient, providing the research would not be substantially modified by participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 7a, indicate "Next Page" and provide the information on a plain sheet of paper after the Face Page.

If the applicant organization has an approved Multiple Project Assurance on file with the Office for Protection from Research Risks (OPRR) but, at the time of application, plans for the involvement of human subjects are so indefinite that IRB review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 7a. If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval, or a designation of exemption, has been submitted to the PHS awarding component.

Item 8. Vertebrate Animals. In many instances, trainees supported by institutional training grants will be participating in research projects for which the Institutional Animal Care and Use Committee (IACUC) review is complete. This review is sufficient, providing the research would not be substantially modified by participation of a trainee. The appropriate grants must be identified along with the IACUC review dates. If space is insufficient in Item 8a, indicate "Next Page" and provide the information on a plain sheet of paper after the Face Page.

If the applicant organization has an approved Animal Welfare Assurance on file with OPRR but, at the time of application, plans for the involvement of vertebrate animals are so indefinate that IACUC review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 8a. If an award is made, vertebrate animals may **not** be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

Item 11. Inventions and Patents. Not applicable.

Item 14. The program director's signature assures that postdoctoral trainees have been informed of payback requirements associated with the NRSA program.

2. Next Budget Period (Form Page 2)

Use the NRSA substitute budget page, and follow the instructions below, to request direct costs for the next budget period. Any additional information should be provided on Form Page 3.

Stipends

Enter the number of trainees and stipend amount for each trainee. Identify, by name, all trainees to be continued and new trainees to whom a commitment has been made for the next budget period.

Tuition, Fees, and Insurance

Itemize tuition, individual fees, and **self-only** medical insurance. If tuition varies, e.g., in-state, out-of-state, or student status, identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition, fees, and self-only medical insurance may be requested only to the extent that the same resident or nonresident tuition, fees, and medical insurance are charged to regular non-Federally-supported students.

Trainee Travel

State the purpose of any travel, give the number of trips involved, the destinations, and the number of individuals for whom funds are requested. Justify foreign travel in detail, describing its importance to the training experience.

Training-Related Expenses

Funds to defray other costs of training, such as staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the predetermined amount per predoctoral and postdoctoral trainee. Enter the total dollar figure only. No further itemization or explanation is required.

3. Budget Justification (Form Page 3)

Current Budget Period

Indicate whether all stipends awarded for the current budget period will be used and explain any estimated unexpended balance.

4. Biographical Sketch (Form Page 4)

Provide biographical sketches **only** for newly added professionals.

5. Other Support

Not applicable.

6. Progress Report Summary (Form Page 5)

Use the following instructions to prepare a progress report, which provides a brief presentation of the accomplishments and changes in the training program during the reporting period, following the outline below:

a. Training Program

Provide a brief description of the training objectives and goals for the reporting period. Highlight progress in implementation and developments or changes that have occurred. Note any difficulties encountered by the program. Describe changes in the program for the next budget period, including changes in training faculty and significant changes in available space and/or facilities. Include, as appropriate, significant new training content, procedures or experiences, and indicate how these aid in strengthening and realizing the objectives and goals of the program. Describe the nature of the instructions in the responsible conduct of science and the extent of trainee and faculty participation.

b. Study Subjects

Provide data on the number of study subjects **only** if the trainees have participated in research involving human subjects that has not been reported within the progress report of another PHS-supported project.

c. Trainees

1) Use NRSA additional Form Page 5 (Summary of Trainees) to provide the following information. For trainees who have left the program, and those trainees who have completed their training during this reporting period, indicate the degree earned and the nature of their current positions. Include the name of the institution, type, and research involvement

of the position, and any other relevant information.

At the bottom of this page, summarize information on the gender and racial/ethnic distribution of the trainees supported on this grant during the reporting period.

2) Include a brief paragraph that describes the research project and course work of current trainees. Provide the name of the faculty supervisor.

3) List the titles and complete references (author(s), journal or book, year, page number) of all trainee publications not previously reported. This includes manuscripts submitted or accepted for publication.

7. Checklist (Form Page 6)

Facilities and Administration (Indirect) Costs

Facilities and Administration (F&A) costs under institutional NRSAs, other than those issued to State or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment is also excluded on those training grants where Training Related Expenses are not calculated on a lump-sum basis, such as the MARC Honors Undergraduate Research Training Grant. State and local government agencies will receive awards at their full Facilities and Administration cost rate.

8. Personnel Report (Form Page 7)

Not applicable.